

	
AETNA BETTER HEALTH® Coverage Policy/Guideline	
Name: Adempas	Page: 1 of 5
Effective Date: 2/28/2025	Last Review Date: 1/2025
Applies to: <div> <input checked="" type="checkbox"/> Illinois <input type="checkbox"/> Florida <input checked="" type="checkbox"/> Florida Kids </div> <div> <input checked="" type="checkbox"/> New Jersey <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Michigan </div> <div> <input checked="" type="checkbox"/> Pennsylvania Kids <input type="checkbox"/> Virginia <input type="checkbox"/> Kentucky PRMD </div>	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Adempas under the patient’s prescription drug benefit.

Description:

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

Pulmonary Arterial Hypertension (PAH)

Adempas is indicated for the treatment of adults with pulmonary arterial hypertension (PAH), (World Health Organization [WHO] Group 1), to improve exercise capacity, WHO functional class and to delay clinical worsening. Efficacy was shown in patients on Adempas monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominately patients with WHO functional class II-III and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Chronic Thromboembolic Pulmonary Hypertension (CTEPH)

Adempas is indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH), (WHO Group 4) after surgical treatment, or inoperable CTEPH to improve exercise capacity and WHO functional class.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Adempas



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Policy/Guideline:

Prescriber Specialties

This medication must be prescribed by or in consultation with a pulmonologist or cardiologist.

Coverage Criteria

Pulmonary Arterial Hypertension (PAH)^{1,3-5}

Authorization of 12 months may be granted for treatment of PAH when ALL of the following criteria are met:

- Member has PAH defined as WHO Group 1 class of pulmonary hypertension (refer to Appendix).
- PAH was confirmed by right heart catheterization with all of the following pretreatment results:
 - Mean pulmonary arterial pressure (mPAP) > 20 mmHg
 - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
 - Pulmonary vascular resistance (PVR) > 2 Wood units
- Patient is unable to take the required number of formulary alternatives (3) for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication

Chronic Thromboembolic Pulmonary Hypertension (CTEPH)^{1-4,6,7}

Authorization of 12 months may be granted for treatment of CTEPH when ALL of the following criteria are met:

- Member has CTEPH defined as WHO Group 4 class of pulmonary hypertension (refer to Appendix).
- Member has either of the following:
 - Recurrent or persistent CTEPH after pulmonary endarterectomy (PEA)
 - Inoperable CTEPH with diagnosis confirmed by BOTH of the following:
 - Computed tomography (CT)/magnetic resonance imaging (MRI) angiography or pulmonary angiography
 - Pretreatment right heart catheterization with all of the following results:
 - mPAP > 20 mmHg
 - PCWP ≤ 15 mmHg



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- PVR > 2 Wood units

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are currently receiving the requested medication through a paid pharmacy or medical benefit, and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Appendix

WHO Classification of Pulmonary Hypertension (PH)⁴

Note: Patients with heritable PAH or PAH associated with drugs and toxins might be long-term responders to calcium channel blockers.

Group 1: Pulmonary Arterial Hypertension (PAH)

- Idiopathic
 - Long-term responders to calcium channel blockers
- Heritable
- Associated with drugs and toxins
- Associated with:
 - Connective tissue disease
 - Human immunodeficiency virus (HIV) infection
 - Portal hypertension
 - Congenital heart disease
 - Schistosomiasis
- PAH with features of venous/capillary (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
- Persistent PH of the newborn

Group 2: PH associated with Left Heart Disease

- Heart failure:
 - With preserved ejection fraction
 - With reduced or mildly reduced ejection fraction
 - Cardiomyopathies with specific etiologies (i.e., hypertrophic, amyloid, Fabry disease, and Chagas disease)
- Valvular heart disease:
 - Aortic valve disease
 - Mitral valve disease



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- Mixed valvular disease
- Congenital/acquired cardiovascular conditions leading to post-capillary PH

Group 3: PH associated with Lung Diseases and/or Hypoxia

- Chronic obstructive pulmonary disease (COPD) and/or emphysema
- Interstitial lung disease
- Combined pulmonary fibrosis and emphysema
- Other parenchymal lung diseases (i.e., parenchymal lung diseases not included in Group 5)
- Nonparenchymal restrictive diseases:
 - Hypoventilation syndromes
 - Pneumonectomy
- Hypoxia without lung disease (e.g., high altitude)
- Developmental lung diseases

Group 4: PH associated with Pulmonary Artery Obstructions

- Chronic thromboembolic PH
- Other pulmonary artery obstructions:
 - Sarcomas (high- or intermediate-grade or angiosarcoma)
 - Other malignant tumors (e.g., renal carcinoma, uterine carcinoma, germ-cell tumors of the testis)
 - Non-malignant tumors (e.g., uterine leiomyoma)
 - Arteritis without connective tissue disease
 - Congenital pulmonary artery stenoses
 - Hydatidosis

Group 5: PH with Unclear and/or Multifactorial Mechanisms

- Hematological disorders, including inherited and acquired chronic hemolytic anemia and chronic myeloproliferative disorders
- Systemic disorders: Sarcoidosis, pulmonary Langerhans cell histiocytosis, and neurofibromatosis type 1
- Metabolic disorders, including glycogen storage diseases and Gaucher disease
- Chronic renal failure with or without hemodialysis
- Pulmonary tumor thrombotic microangiopathy
- Fibrosing mediastinitis
- Complex congenital heart disease



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Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit:

- Adempas 0.5 mg tablets: 90 per 30 days
- Adempas 1 mg tablets: 90 per 30 days
- Adempas 1.5 mg tablets: 90 per 30 days
- Adempas 2 mg tablets: 90 per 30 days
- Adempas 2.5 mg tablets: 90 per 30 days

References:

1. Adempas [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; January 2023.
2. Jenkins D, Mayer E, Screaton N, Madani M. State-of-the-art chronic thromboembolic pulmonary hypertension diagnosis and management. *Eur Respir Rev.* 2012;21(123):32-39.
3. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J.* 2019;53(1):1801913. doi: 10.1183/13993003.01913-2018
4. Kovacs G, Bartolome S, Denton CP, et al. Definition, classification and diagnosis of pulmonary hypertension. *Eur Respir J.* 2024;64(4):2401324. doi: 10.1183/13993003.01324-2024
5. Chin KM, Gaine SP, Gerges C, et al. Treatment algorithm for pulmonary arterial hypertension. *Eur Respir J.* 2024;64(4):2401325. doi: 10.1183/13993003.01325-2024
6. Kim NH, D'Armini AM, Delcroix M, et al. Chronic thromboembolic pulmonary disease. *Eur Respir J.* 2024;64(4):2401294. doi: 10.1183/13993003.01294-2024
7. Rajagopal S, Bogaard HJ, Elbaz MSM, et al. Emerging multimodality imaging techniques for the pulmonary circulation. *Eur Respir J.* 2024;64(4):2401128. doi: 10.1183/13993003.01128-2024